

# **Exhibit A**

Form 10-K

Page 1 of 10

0-K 1 d10k.htm FORM 10-K

[Table of Contents](#)

---

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

## FORM 10-K

Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-33139

---

## THERASENSE, INC.

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
incorporation or organization)

**No. 94-3267373**  
(I.R.S. Employer  
Identification No.)

**1360 South Loop Road, Alameda, CA 94502**  
(Address of principal executive offices)

**Registrant's telephone number, including area code: (510) 749-5400**

**Securities registered pursuant to Section 12(b) of the Act: None**

**Securities registered pursuant to Section 12(g) of the Act:**  
**Common stock, \$0.001 par value**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934): Yes ☐ No ☒.

The aggregate market value of the 36,292,629 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price, as reported on the Nasdaq National Market, as of the last business day of registrant's most recently completed second fiscal quarter (June 30, 2003), was approximately \$362,926,290. Registrant has no non-voting common equity.

There were 42,566,797 shares of the registrant's Common Stock \$0.001 par value, issued and outstanding as of March 1, 2004.

Table of Contents

may not be issued as patents in a form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by employees. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Even if our intellectual property rights are adequately protected, litigation may be necessary to enforce our intellectual property rights, which could result in substantial costs to us and result in a substantial diversion of management attention. If our intellectual property is not adequately protected, our competitors could use our intellectual property to enhance their products. This would harm our competitive position, decrease our market share and otherwise harm our business.

**The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our products may not be successful and our business would be harmed.**

We rely on licenses to use various technologies that are material to our business. We do not own the patents that underlie these licenses. The licenses from Asulab, SA and Inverness Medical Innovations, Inc. grant us the right under specific patents to make and sell diagnostic devices for diabetes monitoring that contain the inventions claimed in the licensed patents. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our licensors abiding by the terms of those licenses. In addition, we often do not control the prosecution of the patents to which we hold licenses or the strategy for determining when such patents should be enforced. As a result, we are largely dependent upon our licensors to determine the appropriate strategy for prosecuting and enforcing those patents.

**If we are unable to continue to develop innovative products in the glucose monitoring market, our business would be harmed.**

The glucose monitoring market is subject to rapid technological change and product innovations. Our products are based on our proprietary technology, but our competitors may succeed in developing or marketing products that will be technologically superior to ours or be more competitive with regard to product features. In addition, over \$91 billion is spent annually on the treatment of diabetes and its complications and the National Institutes for Health and other supporters of diabetes research are continually seeking ways to prevent or cure diabetes. Therefore, our products may also be rendered obsolete by technological breakthroughs in diabetes prevention, monitoring or treatment.

We are currently developing additional enhancements for our FreeStyle products. We are also developing new products such as the CozMore Insulin Technology System, a product we are developing with Deltec, Inc. that permits the electronic transmission of a blood glucose reading taken using our FreeStyle blood glucose monitoring technology to Deltec's Cozmo insulin pump, and FreeStyle Navigator, our continuous glucose monitoring system. Marketing of these products will require FDA and other regulatory clearances and approvals. We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. Development of Navigator and other products will require additional research and development expenditures. We may not be successful in developing, marketing or manufacturing these new products.

In addition, several of our competitors are in various stages of development of continuous glucose monitoring products continuous glucose monitoring similar to Navigator, and the FDA has approved three of these products for adjunctive use with *in vitro* blood glucose monitoring systems. If any of our competitors succeeds in developing a continuous glucose monitor that is approved for marketing as a replacement for *in vitro* blood glucose monitoring, this would negatively affect our future revenues.

Similarly, several of our competitors and some new market entrants are developing products that have small sample size requirements, the ability to test on the fingertip and other body sites, or the ability to communicate with an insulin pump. For instance, Bayer Corporation recently launched a blood glucose monitoring system that claims a sample size requirement of less than one microliter and is cleared for testing on certain alternative sites. In addition, Becton, Dickinson has launched a blood glucose monitoring system that claims the same sample size requirement as FreeStyle and communicates with an insulin pump from Medtronic, Inc., the leading provider of such pumps. The successful development and introduction of such products by competitors or new entrants would reduce the product benefits of our FreeStyle products versus the competition and could adversely impact future revenues.

**If we fail to obtain or maintain necessary FDA clearances or approvals for products, or if approvals are delayed, we will be unable to commercially distribute and market our products in the United States.**

Our products are medical devices that are subject to extensive regulation in the United States and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. Either process can be lengthy and expensive. The FDA's

Table of Contents

510(k) clearance process usually takes from four to twelve months from the date the application is complete, but may take longer. Although we have obtained 510(k) clearance for our initial product, FreeStyle, our 510(k) clearance can be revoked if safety or effectiveness problems develop. The premarket approval process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is complete or even longer. However, achieving a completed application is a process that may take numerous clinical trials and require the filing of amendments over time. The FDA acknowledged receipt of our premarket approval submission in November 2003, and the FDA recently accepted the submission for filing. Therefore, even if a product is successfully developed, it may not be commercially available for a number of years. Navigator, our continuous glucose monitoring system under development, will require premarket approval. We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. We may not be able to obtain additional clearances or approvals for Navigator or other products in a timely fashion, or at all. Delays in obtaining clearance or approval could adversely affect our revenues and profitability.

**Modification to our marketed devices may require new 510(k) clearances or premarket approvals. Any modification to an FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any such decision and potentially require us to cease marketing or recall the modified devices until these clearances are obtained.**

Any modification to an FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly premarket approval. The FDA requires every manufacturer to make his determination in the first instance, but the FDA can review any such decision. We have modified certain aspects of FreeStyle since receiving regulatory approval, but we believe that new 510(k) clearances are not required. In the case of certain labeling changes for FreeStyle, the FDA required a new 510(k) clearance which was obtained in December 2001. We may make additional modifications to FreeStyle and future products after they have received clearance or approval, and in appropriate circumstances, determine that new clearance or approval is unnecessary. The FDA may not agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

**If our suppliers or we fail to comply with the FDA's Quality System Regulation, our manufacturing operations could be delayed, and our product sales and profitability could suffer.**

Our manufacturing processes for our FreeStyle test strips, as well as the manufacturing processes utilized by our suppliers of meters, lancets, and control solution, are required to comply with the FDA's Quality System Regulation, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the Quality System Regulation through unannounced inspections. The manufacturing lines for our meters at Flextronics International Ltd. in China have not been inspected to date. If we or one of our suppliers fail a Quality System Regulation inspection, our operations could be disrupted and our manufacturing delayed. If we fail to take adequate corrective action in response to any FDA observations, we could face various enforcement actions, which could include a shut-down of our manufacturing operations and a recall of our products, which would harm our reputation and cause our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

**Our products are subject to product recalls or field corrective actions even after receiving FDA clearance or approval, which would harm our reputation.**

The FDA and similar governmental authorities in other countries have the authority to require the recall of or field corrective actions for our products in the event of material deficiencies or defects in design or manufacture. A government mandated or firm-initiated recall or field corrective action by us could occur as a result of component failures, manufacturing errors or design defects. We commenced a firm-initiated field corrective action due to software bugs associated with the diabetes management features of our FreeStyle Tracker diabetes management system shortly after its launch. Any recall of or material field corrective action for product may divert managerial and financial resources and harm our reputation with customers.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 11, 2004.

THERASENSE, INC.

By: /s/ W. MARK LORTZ

**W. Mark Lortz**  
Chairman of the Board, President  
and Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints W. Mark Lortz, Charles T. Lamos and Robert D. Brownell, and each of them individually, as his attorney-in-fact, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with exhibits hereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in fact, or his substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Title	Date
<u>/s/ W. MARK LORTZ</u> W. Mark Lortz	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 11, 2004
<u>/s/ CHARLES T. LIAMOS</u> Charles T. Lamos	Chief Operating Officer, Chief Financial Officer and Director (Principal Financial Officer and Principal Accounting Officer)	March 11, 2004
<u>/s/ BRADFORD A. BOWLUS</u> Bradford A. Bowlus	Director	March 11, 2004
<u>/s/ ROD F. DAMMEYER</u> Rod F. Dammeyer	Director	March 11, 2004
<u>/s/ ROSS A. JAFFE, M.D.</u> Ross A. Jaffe, M.D.	Director	March 11, 2004
<u>/s/ JONATHAN T. LORD, M.D.</u> Jonathan T. Lord, M.D.	Director	March 11, 2004
<u>/s/ ROBERT R. MOMSEN</u> Robert R. Momsen	Director	March 11, 2004
<u>/s/ RICHARD P. THOMPSON</u> Richard P. Thompson	Director	March 11, 2004

## **Exhibit B**

QuickLinks — Click here to rapidly navigate through this document

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549**

**FORM 10-K**

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2005

Commission file number 1-2189



**Abbott Laboratories**

An Illinois Corporation

36-0698440

(I.R.S. employer identification number)

100 Abbott Park Road  
Abbott Park, Illinois 60064-6400

(847) 937-6100  
(telephone number)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Shares, Without Par Value (including Preferred Stock Purchase Rights)	New York Stock Exchange Chicago Stock Exchange Pacific Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☒ Accelerated Filer ☐ Non-accelerated Filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The aggregate market value of the 1,487,731,767 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of Abbott Laboratories' most recently completed second fiscal quarter (June 30, 2005), was approximately \$72,913,733,900. Abbott has no non-voting common equity.

**The expiration of patent protection and licenses may affect Abbott's future revenues and operating income.**

Many of Abbott's businesses rely on patent and trademark and other intellectual property protection. Although most of the challenges to Abbott's intellectual property have come from other businesses, governments may also challenge intellectual property protections. To the extent Abbott's intellectual property is successfully challenged, invalidated, or circumvented or to the extent it does not allow Abbott to compete effectively, Abbott's business will suffer. To the extent that countries do not enforce Abbott's intellectual property rights or require compulsory licensing of its intellectual property, Abbott's future revenues and operating income will be reduced.

Abbott's principal patents and trademarks are described in greater detail in the sections captioned, "Patents, Trademarks, and Licenses" and "Financial Review," and litigation regarding these patents is described in the section captioned "Legal Proceedings."

**Competitors' intellectual property may prevent Abbott from selling its products or have a material adverse effect on Abbott's future profitability and financial condition.**

Competitors may claim that an Abbott product infringes upon their intellectual property. A successful claim of patent or other intellectual property infringement against Abbott could adversely affect Abbott's profitability or financial condition, in some cases materially. Abbott cannot assure that it does not, in fact, infringe upon other's intellectual property. Resolving an intellectual property infringement claim can be costly and time consuming and may require Abbott to enter into royalty or license agreements. If this should be necessary, Abbott cannot guarantee that it would be able to obtain royalty or license agreements on commercially reasonable terms. A successful claim of patent or other intellectual property infringement could subject Abbott to significant damages or an injunction preventing the manufacture, sale or use of affected Abbott products. Any of these events could have a material adverse effect on Abbott's profitability and financial condition.

**Abbott is subject to cost-containment efforts.**

In the United States and other countries, access to and the cost of human health care products continues to be subject to downward pressure on prices. Cost-containment efforts by the government and private organizations are described in greater detail in the section captioned "Regulation."

In markets outside the United States, Abbott's businesses have experienced downward pressure on product pricing. Many countries, directly or indirectly, through limitations on reimbursement or availability, control the selling price of most health care products. To the extent these cost containment efforts are not offset by greater patient access to healthcare or other factors, Abbott's future revenues and operating income will be reduced.

**Abbott is subject to numerous governmental regulations and it can be costly to comply with these regulations and to develop compliant products and processes.**

Abbott's products are subject to rigorous regulation by the Federal Food and Drug Administration, and numerous other national, supranational, federal and state authorities. The process of obtaining regulatory approvals to market a drug or medical device, particularly from the FDA and certain governmental authorities outside the United States, can be costly and time-consuming, and approvals might not be granted for future products on a timely basis, if at all. Regulation is not static. The suspension, revocation, or adverse amendment of the authority necessary for manufacture, marketing, or sale, and the imposition of additional or different regulatory requirements, such as those affecting labeling can also occur. Delays in the receipt of, or failure to obtain approvals for, future products could result in delayed realization of product revenues and in substantial additional costs.

In addition, no assurance can be given that Abbott will remain in compliance with applicable FDA and other regulatory requirements once clearance or approval has been obtained for a product. These

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Abbott Laboratories has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ABBOTT LABORATORIES**

By /s/ MILES D. WHITE

Miles D. White  
Chairman of the Board and  
Chief Executive Officer  
Date: February 21, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of Abbott Laboratories on February 21, 2006 in the capacities indicated below.

/s/ MILES D. WHITE

Miles D. White  
Chairman of the Board, Chief Executive  
Officer and Director of Abbott Laboratories  
(principal executive officer)

/s/ ROXANNE S. AUSTIN

Roxanne S. Austin  
Director of Abbott Laboratories

/s/ RICHARD A. GONZALEZ

Richard A. Gonzalez  
President and Chief Operating Officer,  
Medical Products Group and  
Director of Abbott Laboratories

/s/ WILLIAM M. DALEY

William M. Daley  
Director of Abbott Laboratories

/s/ JEFFREY M. LEIDEN

Jeffrey M. Leiden  
President and Chief Operating Officer,  
Pharmaceutical Products Group and  
Director of Abbott Laboratories

/s/ W. JAMES FARRELL

W. James Farrell  
Director of Abbott Laboratories

# **Exhibit C**

LEXSEE 1997 U.S. DIST. LEXIS 7260

**GLAXO, INC., GLAXO GROUP LIMITED, Plaintiffs, Counterdefendants, v.  
TORPHARM, INC., APOTEX USA, INC., APOTEX, INC., Defendants, Counter-  
claimants.**

No. 95 C 4686

**UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF  
ILLINOIS, EASTERN DIVISION**

*1997 U.S. Dist. LEXIS 7260*

**May 15, 1997, Decided  
May 18, 1997, DOCKETED**

**DISPOSITION:** [\*1] Motion for summary judgment of defendants TorPharm, Inc., Apotex USA, Inc. and Apotex, Inc. [120-1] granted in part and denied in part. Stay entered in this case vacated.

**CASE SUMMARY:**

**PROCEDURAL POSTURE:** Plaintiff patent holder filed an infringement action under 35 U.S.C.S. § 271(e) against defendant drug company following the filing of an abbreviated new drug application (ANDA) to manufacture a drug also manufactured by the patent holder. The patent holder also sought a declaratory judgment that the product the drug company intended to manufacture under the ANDA infringed another patent. The drug company filed a motion for summary judgment.

**OVERVIEW:** The patent holder claimed that the product to be produced under the drug company's ANDA would infringe two of its patents. The § 271(e) claim applied to a drug under patent '431, while the declaratory judgment action applied to a drug-making process under patent '133. The drug company claimed that the patent holder produced no evidence of infringement because the patent holder's expert did not use the patent claim to prove infringement. The court held that the patent holder's expert's testimony sufficiently created a triable issue of fact as to infringement of claim 1 of the '431 patent because he found that the drug company's product contained the 29 main peaks listed in the patent. Because the patent holder presented some evidence of infringement by the drug company's product, summary judgment was denied as to the declaratory judgment action. The patent holder did not offer any evidence that demonstrated that the drug company's product met all of the claim limitations of claim 2. The expert failed to use the

proper methodology to analyze the patent, so the court granted the drug company's motion for summary judgment as to claim 2.

**OUTCOME:** The court granted the motion for summary judgment of the drug company as to claim 2 of the '431 patent and denied the motion as to claim 1 of the '431 patent and as to the patent holder's declaratory judgment action.

**LexisNexis(R) Headnotes**

*Civil Procedure > Summary Judgment > Burdens of Production & Proof > Nonmovants*

*Civil Procedure > Summary Judgment > Standards > General Overview*

[HN1] On a motion for summary judgment, the entire record is considered with all reasonable inferences drawn in favor of the nonmovants and all factual disputes resolved in favor of the nonmovants. The burden of establishing a lack of any genuine issue of material fact rests on the movant. The nonmovant, however, must make a showing sufficient to establish any essential element for which it will bear the burden of proof at trial. The movant need not provide affidavits or deposition testimony showing the nonexistence of such essential elements. Also, it is not sufficient to show evidence of purportedly disputed facts if those facts are not plausible in light of the entire record.

*Criminal Law & Procedure > Criminal Offenses > Controlled Substances > General Overview*

*Patent Law > Infringement Actions > Defenses > Experimental Use & Testing*

1997 U.S. Dist. LEXIS 7260, \*

***Patent Law > Remedies > Bad Faith Enforcement***

[HN2] 35 U.S.C.S. § 271(e)(2) provides that submitting an abbreviated new drug application is an act of infringement for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under such act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

***Patent Law > Inequitable Conduct > General Overview******Patent Law > Infringement Actions > Defenses > Experimental Use & Testing******Patent Law > Remedies > Bad Faith Enforcement***

[HN3] 35 U.S.C.S. § 271(e)(2) requires an infringement inquiry focused on what is likely to be sold following Food and Drug Administration approval. As in a normal patent infringement case, the burden is on the patent holder to prove by a preponderance of the evidence that what is to be sold infringes. The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the abbreviated new drug application (ANDA) applicant will likely market if its application is approved, an act that has not yet occurred.

***Civil Procedure > Justiciability > Case or Controversy Requirements > Actual Disputes******Patent Law > Infringement Actions > Burdens of Proof******Patent Law > Infringement Actions > Infringing Acts > General Overview***

[HN4] A patentee may seek a declaration that a person will infringe a patent in the future, but there must be an actual controversy for a district court to have jurisdiction. To demonstrate that an actual controversy exists, a patentee must show that (1) the defendant must be engaged in an activity directed toward an infringement charge or be making meaningful preparation for such activity; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.

***Patent Law > Infringement Actions > Claim Interpretation > Fact & Law Issues******Patent Law > Infringement Actions > Claim Interpretation > Scope******Patent Law > Infringement Actions > Infringing Acts > General Overview***

[HN5] An analysis of infringement requires two steps. The first step is determining the meaning and scope of

the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing. The first step, claim construction, is a question of law for the court.

***Patent Law > Infringement Actions > Claim Interpretation > General Overview***

[HN6] It is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claim of the patent.

**COUNSEL:** For GLAXO INC, plaintiff: George A. Zelcs, Dean Scott Rauchwerger, James F. Smith, Clausen, Miller, Gorman, Caffrey & Witous, P.C., Chicago, IL. Stephen B. Judlowe, Ira B. Winkler, Janet B. Linn, Brian P. Murphy, William G Todd, Scott G Lindvall, Daniel R Schechter, Hopgood, Calinafde, Kalil, Blaustein & Judlowe, New York, NY. For GLAXO GROUP LIMITED, plaintiff: George A. Zelcs, (See above), Dean Scott Rauchwerger, (See above), James F. Smith, (See above). Stephen B. Judlowe, (See above), Ira B. Winkler, (See above), Janet B. Linn, (See above), Brian P. Murphy, (See above), William G Todd, (See above), Scott G Lindvall, (See above), Daniel R Schechter, (See above).

For TORPHRAM, INC., defendant: Hugh L. Moore, Keith D. Parr, Christine J. Siwik, Lord, Bissell & Brook, Chicago, IL. David G Greene, Lord, Bissell & Brook, Atlanta, GA. For APOTEX USA, INC., defendant: Hugh L. Moore, (See above), Keith D. Parr, (See above), Christine J. Siwik, (See above). David G Greene, (See above). For APOTEX, INC., defendant: [\*2] Hugh L. Moore, (See above), Keith D. Parr, (See above), Christine J. Siwik, (See above). David G Greene, (See above).

For TORPHRAM, INC., counter-claimant: Keith D. Parr, Christine J. Siwik, Lord, Bissell & Brook, Chicago, IL. For APOTEX USA, INC., counter-claimant: Keith D. Parr, (See above), Christine J. Siwik, (See above).

For GLAXO INC, counter-defendant: George A. Zelcs, James F. Smith, Clausen, Miller, Gorman, Caffrey & Witous, P.C., Chicago, IL. Stephen B. Judlowe, Ira B. Winkler, Janet B. Linn, Brian P. Murphy, Hopgood, Calinafde, Kalil, Blaustein & Judlowe, New York, NY. For GLAXO GROUP LIMITED, counter-defendant: George A. Zelcs, (See above), James F. Smith, (See above). Stephen B. Judlowe, (See above), Ira B. Winkler, (See above), Janet B. Linn, (See above), Brian P. Murphy, (See above).

**JUDGES:** William T. Hart, UNITED STATES DISTRICT JUDGE

**OPINIONBY:** William T. Hart

**OPINION:**

**MEMORANDUM OPINION AND ORDER**

Glaxo, Inc. and Glaxo Group Limited (collectively, "Glaxo") bring this action against TorPharm Inc., Apotex USA, Inc. and Apotex, Inc. (collectively, "TorPharm"), alleging that TorPharm infringed U.S. Letters Patent 4,521,431 ("the '431 patent") under 35 U.S.C. § [\*3] 271(e) ("§ 271(e)") by filing an abbreviated new drug application ("ANDA"). Glaxo also seeks a declaratory judgment that the product TorPharm intends to manufacture under the ANDA infringes U.S. Letters Patent No. 4,672,133 ("the '133 patent"). Presently pending is TorPharm's motion for summary judgment.

**I. FACTUAL BACKGROUND**

Glaxo developed and currently manufactures the well-known anti-ulcer medication, Zantac. The active ingredient in Zantac is the aminoalkyl furan derivative ranitidine hydrochloride ("RHCl"). RHCl is the subject of the '431 patent, the '133 patent and another patent owned by Glaxo, U.S. Patent No. 4,128,658 ("the '658 patent").

RHCl is a salt that occurs in at least two distinct crystalline forms. In 1978, Glaxo was granted the '658 patent, which discloses a method for the production of a form of RHCl known as Form 1 RHCl. The '658 patent expires on July 25, 1997. At the time the patent application was filed, Glaxo did not know that RHCl could occur in more than one crystalline form.

Over the course of the next few years, Glaxo made several batches of RHCl in a pilot plant for further testing and for use in clinical investigations. In 1980, Glaxo [\*4] scientists produced the thirteenth pilot batch of RHCl. Glaxo determined that this material possessed a different crystalline form than Form 1 RHCl. Glaxo decided that this second crystalline form of RHCl, known as Form 2 RHCl, was preferable to Form 1 RHCl because it possessed better filtering and drying characteristics than Form 1 RHCl. Form 2 RHCl is the active ingredient in Zantac.

Glaxo sought and received two patents covering Form 2 RHCl. The '431 patent, issued in 1985, covers a specific crystalline form or "polymorph" of RHCl. The '431 patent will expire in 2002. The '133 patent covers the processes for making Form 2 RHCl and will expire in 2004. The claims in both the '431 and '133 patents describe Form 2 RHCl by means of a specific, 29-peak infrared spectrum. Claim 2 of the '431 patent further

characterizes Form 2 RHCl by a 32-intensity x-ray powder diffraction pattern.

Anticipating the expiration of the '658 patent, TorPharm filed an ANDA with the U.S. Food and Drug Administration ("FDA") on June 5, 1995. TorPharm sought approval to market Form 1 RHCl after the expiration of the '658 patent. As part of its application, TorPharm submitted a "Paragraph IV certification" [\*5] stating that Glaxo's patents will "not be infringed by the manufacture, use or sale of the drug for which the [ANDA] is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Pursuant to 21 U.S.C. § 505(j), TorPharm notified Glaxo of its ANDA filing and the contents of its certifications.

On August 14, 1995, Glaxo sued TorPharm for infringement of the '431 patent under § 271(e). Glaxo believes that TorPharm's product contains Form 2 RHCl in addition to Form 1 RHCl. Glaxo also seeks a declaratory judgment that TorPharm would infringe the '133 patent under 35 U.S.C. § 271(g) by manufacturing and selling the drug for which TorPharm seeks approval. TorPharm moves for summary judgment on both claims on the grounds that Glaxo has no evidence that TorPharm's product infringes any of the claims of the '431 or '133 patents.

**II. DISCUSSION**

[HN1] On a motion for summary judgment, the entire record is considered with all reasonable inferences drawn in favor of the nonmovants and all factual disputes resolved in favor of the nonmovants. *Lane Bryant, Inc. v. United States*, 35 F.3d 1570, 1574 (Fed. Cir. 1994); *Oxman v. WLS-TV*, 846 F.2d 448, 452 (7th Cir. 1988); *Jakubiec v. Cities Service* [\*6] Co., 844 F.2d 470, 471 (7th Cir. 1988). The burden of establishing a lack of any genuine issue of material fact rests on the movant. *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1560-61 (Fed. Cir. 1995); *Jakubiec*, 844 F.2d at 473. The nonmovant, however, must make a showing sufficient to establish any essential element for which it will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). The movant need not provide affidavits or deposition testimony showing the non-existence of such essential elements. *Id.* at 324. Also, it is not sufficient to show evidence of purportedly disputed facts if those facts are not plausible in light of the entire record. See *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1191 (Fed. Cir. 1993); *Covalt v. Carey Canada, Inc.*, 950 F.2d 481, 485 (7th Cir. 1991); *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 476-77 (7th Cir. 1988).

Glaxo brings its infringement claim under § 271(e). Section 271(e) is part of the Hatch-Waxman Act, which

1997 U.S. Dist. LEXIS 7260, \*

allows generic drug makers to market generic versions [\*7] of patented drugs as soon as possible after expiration of the patent. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1257, 1997 WL 156592, \*6 (Fed. Cir. 1997). At the same time, patent holders are provided with limited extensions of patent term in order to recover a portion of the market exclusivity lost during the lengthy process of development and FDA review. *Id.*

[HN2] Section 271(e)(2) provides that submitting an ANDA is an act of infringement for a drug claimed in a patent or the use of which is claimed in a patent "if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2). The Federal Circuit has held that [HN3] "the statute requires an infringement inquiry focused on what is likely to be sold following FDA approval." *Novopharm*, 1997 WL 156592 at \*6. As in a normal patent infringement case, the burden is on the patent holder to prove by a preponderance of the evidence that what is to be sold infringes. *Id.* "The only difference in actions brought under § 271(e)(2) [\*8] is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Id.* at \*8.

Glaxo, however, could not bring a § 271(e) claim for infringement of the '133 patent, because § 271(e) authorizes only those claims directed to drugs or methods of using drugs. *Id.* at \*9. The '133 patent is a process patent, which discloses a method for making a drug, and hence is not covered under § 271(e). Thus, Glaxo has brought a declaratory judgment action seeking a determination that TorPharm's manufacture and sale of RHCl, as potentially approved by the FDA, would infringe the '133 patent.

[HN4] "A patentee may seek a declaration that a person will infringe a patent in the future," but there must be an actual controversy for a district court to have jurisdiction. *Id.* To demonstrate that an actual controversy exists, a patentee must show that

"(1) the defendant must be engaged in an activity directed toward . . . an infringement charge . . . or be making meaningful preparation for such activity; and (2) acts of the defendant [\*9] must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming."

*Id.* at \*10 (quoting *Lang v. Pacific Marine and Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990)). Since there is no question that TorPharm seeks imminent FDA approval to sell a form of RHCl within the near future, the actual controversy requirement is met and Glaxo's declaratory judgment action will be entertained. See *id.*

[HN5] An analysis of infringement requires two steps. "The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). The first step, claim construction, is a question of law for the court. *Id.* at 976-79.

The Federal Circuit has already considered the construction of the claims of the '431 and '133 patents in another case brought by Glaxo. *Novopharm, Ltd.*, 1997 WL 156592 at \*6. In 1994, Novopharm, Ltd. filed [\*10] an ANDA seeking approval to market Form 1 RHCl. Similar to this action, Glaxo sued Novopharm for infringement under § 271(e)(2) of the '431 patent and sought a declaratory judgment that the drug for which Novopharm sought approval would infringe the '133 patent. After a bench trial, the district court entered judgment for Novopharm on all of Glaxo's claims after finding that Glaxo did not prove infringement of its patents. *Glaxo, Inc. v. Novopharm, Ltd.*, 931 F. Supp. 1280, 1286 (E.D.N.C. 1996). Glaxo appealed the district court's decision.

Although the Federal Circuit disagreed with the district court's construction of the claims of the '431 and '133 patents, it affirmed the district court's ruling that Glaxo's proof was not sufficient to prove infringement. In reversing the district court's claims construction, the Federal Circuit held that the '431 and '133 patents were not limited to pure Form 2 RHCl, i.e., the claims cover products containing a mixture of Form 2 RHCl and Form 1 RHCl. *Novopharm*, 1997 WL 156592 at \*3. As to the infringement determination, Glaxo had argued at trial that the district court must analyze infringement based upon a single infrared peak at [\*11] 1045 cm<sup>-1</sup>. The district court rejected Glaxo's single peak argument and the Federal Circuit agreed, reasoning that "the single peak analysis was . . . insufficient because . . . in order to prove infringement Glaxo was required to establish the presence of each limitation of the asserted claims." Moreover, the Federal Circuit stated that "Glaxo knew that its decision to claim Form 2 RHCl according to its IR [infrared] and x-ray powder diffraction characteristics would later control the nature of the evidence necessary to prove infringement." *Id.*

1997 U.S. Dist. LEXIS 7260, \*

Claim 1 of the '431 patent claims "Form 2 ranitidine hydrochloride characterized by an infra-red spectrum as a mull in mineral oil showing the following main peaks. . . ." A table of 29 main peaks in the infrared spectrum are listed. Claim 2, which is dependent on claim 1, claims

Form 2 ranitidine hydrochloride according to claim 1 further characterized by the following x-ray powder diffraction pattern expressed in terms of "d" spacings and relative intensities . . . and obtained by the Debye Scherrer method in a 114.6 mm diameter camera by exposure for 12 hours to CoK[a] radiation and for 2 hours to CuK $\alpha$  radiation.

A [\*12] table of referenced 32 d-spacings and their relative intensities are listed in claim 2.

TorPharm argues that it is entitled to summary judgment because Glaxo has failed to put forth any evidence that any of the 29 main peaks listed in claim 1 are present in its product's infrared spectrum or that the x-ray diffraction of TorPharm's product contains the 32 d-spacings listed in claim 2 of the '431 patent. As evidence of infringement, Glaxo offers the opinions and tests of Dr. Thomas Niemczyk as to claim 1 and Dr. Peter Stephens as to claim 2. TorPharm, however, contends that their opinions do not constitute admissible evidence of infringement and, as a result, Glaxo has no evidence that TorPharm's product infringes Glaxo's patents.

#### **A. Claim 1 - Infrared Spectrum with 29 Main Peaks**

To carry its burden as to claim 1 of the '431 patent, Glaxo must submit some evidence showing that the infrared spectrum of TorPharm's product consists of the 29 main peaks listed in claim 1. Glaxo submits the opinion and test results of Dr. Thomas Niemczyk as evidence of infringement. TorPharm argues that Niemczyk's results do not raise a triable issue of fact because Niemczyk compared TorPharm's [\*13] product against an embodiment of the patent, rather than against the limitations of the claim. Both parties agree that Niemczyk used a reference sample that he created by constructing a statistical model based on his analysis of samples of Form 1 and Form 2 RHCl provided by Glaxo. Niemczyk's reference sample was then compared against TorPharm's product. According to TorPharm, this violates the basic rule that proof of infringement must be based upon a comparison of the accused product against the claims of the patent, not against an embodiment.

The Federal Circuit has consistently held that [HN6] "it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claim of the patent." E.g., *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994); *Martin v. Barber*, 755 F.2d 1564, 1567 (Fed. Cir. 1985). In *Zenith*, the claim at issue specified an x-ray diffraction pattern consisting of 37 lines of relative intensities. The reference pattern exhibited by plaintiff's sample consisted of a table [\*14] of only 30 lines of relative intensities. The Federal Circuit reversed the district court's finding of infringement based upon the improper comparison.

Although Glaxo admits that Niemczyk gathered his reference data from an embodiment, Glaxo contends that the *Zenith's* concerns are not implicated because Niemczyk confirmed that his analysis used all of the 29 main peaks contained in claim 1. Niemczyk's expert report and testimony, however, are confusing as to the role the 29 main peaks played in his analysis. At his deposition, Niemczyk stated that he did not use the table of main peaks in claim 1 and he did not know what was meant by "main peaks," although this phrase appears in the language of claim 1. In his expert report, Niemczyk stated that he created a calibration model from samples of Form 1 and Form 2 RHCl by implementing a Partial Least Squares ("PLS") algorithm. This model was used to determine that TorPharm's sample contained .5 percent Form 2 RHCl. Niemczyk concluded "the presence of Form 2 in TorPharm's ranitidine hydrochloride necessarily indicates that all of the 29 infrared bands characterizing Form 2 are present." At first glance, it appears that Niemczyk concludes [\*15] that the 29 main peaks are present only because he already determined through use of a statistical model that TorPharm's product contained Form 2 RHCl. In other words, Niemczyk's methodology did not utilize the 29 main peaks in either analyzing the reference sample or comparing the reference sample to TorPharm's product.

In an affidavit submitted in connection with this motion, however, Niemczyk stated that the PLS calibration model contained the 29 main peaks listed in claim 1 of the patent and that his infrared analysis confirmed the presence of all 29 main peaks in TorPharm's product. TorPharm responds that Niemczyk's affidavit cannot be considered because it contradicts his prior deposition testimony, in which he stated that he did not use the main peak information in claim 1. See *Bank of Illinois v. Allied Signal Safety Restraint Systems*, 75 F.3d 1162, 1168 (7th Cir. 1996); *Adelman-Tremblay v. Jewel Cos., Inc.*, 859 F.2d 517, 520-21 (7th Cir. 1988) (party cannot cre-

ate a genuine issue of material fact by submitting an affidavit which contradicts prior deposition testimony).

Because the answer as to whether Niemczyk has used the 29 main peaks as a basis for identifying [\*16] Form 2 RHCl in TorPharm's product is essentially a judgment as to the credibility of Glaxo's expert, it would not be proper to decide this question on a motion for summary judgment. Inconsistencies in Niemczyk's testimony will be resolved in favor of Glaxo. Construing the evidence in the light most favorable to Glaxo, Niemczyk's affidavit could be seen as a further explanation of his methodology, rather than a direct contradiction. Thus, Niemczyk's opinion and test results will not be disregarded on this basis.

Second, TorPharm argues that claim 1 defines a basic methodology that Glaxo must follow to prove infringement: Glaxo must show all 29 main peaks can be visually identified in a mull in mineral oil. TorPharm contends that Niemczyk impermissibly "employed a complex, computerized method of mathematical calculation, consisting of various statistical principles, to 'predict' the existence of Form 2 RHCl in TorPharm's product. TorPharm asserts that Niemczyk's opinion and results should not be considered because Niemczyk failed to follow the limitation in claim 1 that all 29 main peaks must be visually identified in a mull in mineral oil.

Glaxo acknowledges that Niemczyk has not [\*17] attempted to empirically identify, i.e., through direct visual observation, whether TorPharm's product contains the 29 main peaks listed in claim 1. Niemczyk testified, however, that he has determined that all 29 main peaks are present in TorPharm's product as a result of a PLS infrared spectral analysis. Glaxo contends that it is not limited to conventional, visual analysis of spectral data to prove infringement. Glaxo argues that visual analysis is inaccurate where, as here, the unknown sample is a mixture of compounds. Niemczyk testified that an unknown compound can be identified by visually comparing the infrared spectrum of the unknown sample with the infrared spectra of known compounds. Niemczyk further testified that when an infrared spectral analysis is performed on a mixture of chemical compounds, as opposed to an isolated chemical compound, the spectrum of the mixture of compounds will be different from the individual spectrum for each compound. Niemczyk stated that analysis by a visual comparison of the infrared spectrum of the mixture with the spectra of known compounds is difficult and imprecise.

Niemczyk sets forth the alternate testing procedure he used with the [\*18] sample of TorPharm's product in his expert report. After obtaining the spectral data from TorPharm's sample, Niemczyk used a multivariate calibration method, Partial Least Squares, to determine that

infringement existed. A Partial Least Squares or PLS calibration correlates the changes in the spectra obtained from calibration sample with the known property, in this case Form 2 RHCl. Dr. Niemczyk concluded from his PLS analysis that the sample of TorPharm's product that he tested contained approximately .5 percent Form 2 RHCl.

The question of permissible methodology is complicated because the Federal Circuit has definitively held that the '431 patent covers a mixture of Form 1 and Form 2 RHCl and that the infrared characteristics defined in the claim "controls" the method of proof. *Novopharm, 1997 WL 156592* at \*3. Yet if Glaxo is right that conventional infrared analysis is inaccurate on a mixture of Form 1 and Form 2 RHCl -- and no opinion is expressed as to whether it is -- then Glaxo is left with the problem of how to prove that a mixture of Form 1 and Form 2 RHCl infringes its patents.

Glaxo's argument in favor of its methodology boils down to a contention that Niemczyk used [\*19] the technique described in claim 1 to obtain the spectrum data on TorPharm's sample and he used PLS only to interpret the data. This inference is not unreasonable in light of the submitted testimony of Niemczyk. Claim 1 does not specifically state that identification of the main peaks must be visual; it only states that Form 2 RHCl is characterized by a mull in mineral oil "showing" the 29 main peaks. If reading the infrared results visually is inconclusive, Glaxo may be able to satisfy its burden of proof by presenting a more accurate method interpretation of the infrared spectrum of TorPharm's product to demonstrate infringement. According to Niemczyk, this method is advantageous because it separately analyzes the infrared spectrum of each component in the mixture. In addition, on a motion for summary judgment, the factual question of the accuracy of Niemczyk's interpretation of the infrared spectrum of TorPharm's product will be resolved in Glaxo's favor. Thus, to the extent that Niemczyk's analysis merely interprets the infrared spectrum of TorPharm's product rather than deviates from a method of proof which demonstrates infringement by showing the presence of the 29 main peaks [\*20] in the infrared spectrum of TorPharm's product, Glaxo's evidence will not be rejected on a motion for summary judgment.

TorPharm offers a final reason for granting summary judgment in its favor in its reply memorandum to Glaxo's opposition memorandum. TorPharm asserts that its specification in its ANDA requires a polymorphic purity of 99.37%. TorPharm asserts that this level of purity demonstrates non-infringement because the Federal Circuit affirmed Novopharm even though Glaxo brought forth evidence that Novopharm's polymorphic purity specification would permit it to market a Form 1

1997 U.S. Dist. LEXIS 7260, \*

RHCl product with a polymorphic purity as low as 90 percent. Glaxo itself asserts that TorPharm's product contains only .5 percent Form 2 RHCl. In *Novopharm*, however, the Federal Circuit expressly noted that "the district court did not decide whether small amounts of Form 2 RHCl in a mixture with Form 1 RHCl would infringe the '431 patent." *Novopharm*, 1997 WL 156592 at \*13 n.1. In any event, TorPharm has raised the issue in its reply memorandum, rather than its motion, and has offered no other authority supporting its position. Thus, the issue of whether a de minimis amount of Form 2 [\*21] RHCl infringes the '431 patent is reserved for further consideration.

Niemczyk's testimony sufficiently creates a triable issue of fact as to infringement of claim 1 of the '431 patent. Summary judgment will be denied as to claim 1 of Glaxo's claim for infringement of the '431 patent. Because Glaxo has presented some evidence of infringement by TorPharm's product, summary judgment will also be denied as to Glaxo's declaratory judgment action.

#### **B. Claim 2 - 32 D-Spacings in X-Ray Diffraction Pattern**

TorPharm asserts that Glaxo has failed to present any admissible evidence of infringement of claim 2 of the '431 patent because, similar to its argument as to claim 1, its expert did not use the methodology specified in the claim. Claim 2, unlike claim 1, expressly identifies the method by which x-ray diffraction pattern must be demonstrated -- the claim states that the pattern must be "obtained by the Debye Scherrer method in a 114.6 mm diameter camera by exposure for 12 hours to CoK[a] radiation and for 2 hours to CuKa radiation." Glaxo's decision to claim Form 2 RHCl according to this methodology controls. See *Novopharm*, 1997 WL 156592 at \*4. Glaxo must use this methodology [\*22] to demonstrate infringement.

Glaxo's expert, Dr. Stephens, did not use the Debye Scherrer method to obtain the x-ray diffraction results Glaxo submits in connection with this motion. Instead, he used the capabilities of the National Synchrotron Light Source at Brookhaven National Laboratory. Dr. Stephens stated in his expert report that "synchrotron radiation sources are generally more intense than laboratory sources." Using the National Synchrotron Light Source, Stephens reports that he identified four of the 32 d-spacings listed in claim 2. Stephens states in his affidavit that on the basis of those matching peaks and his indexing of Form 1 and Form 2 RHCl, it is a "scientific certainty" that TorPharm's product contains Form 2 RHCl. Stephens concludes that "it follows from the presence of Form 2 in [TorPharm's sample] and the results of my indexing of Form 2 that all diffraction peaks at all of

the allowed positions of the Form 2 pattern are present . . . this demonstrates that all 32 diffraction peaks i.e., d-spacings listed in claim of the '431 patent are present." Stephens notes, however, that he could have detected that TorPharm's sample contained Form 2 RHCl by using "x-ray [\*23] film techniques, such as those described in claim 2."

Glaxo has not offered any evidence that demonstrates that TorPharm's product meets all of the claim limitations of claim 2. As an initial matter, Glaxo would be required to use the method prescribed in the patent, the Debye Scherrer method, to prove infringement. Even assuming that Stephens's statement that he could have used the Debye Scherrer method to detect Form 2 RHCl in TorPharm's sample would be acceptable for purposes of surviving summary judgment, Stephens did not find 28 of the 32 d-spacings in the x-ray diffraction pattern of TorPharm's sample. Stephens's circular reasoning -- four d-spacings exist, therefore the product must be Form 2, therefore all 32 d-spacings are present -- is identical to the single peak theory rejected by the Federal Circuit. Glaxo was required to bring forth evidence that TorPharm's product would exhibit an x-ray diffraction pattern with the 32 listed d-spacings using the Debye Scherrer method. Glaxo has failed to do so. Summary judgment will be granted in TorPharm's favor as to claim 2 of the '431 patents.

#### **IT IS THEREFORE ORDERED that:**

(1) The motion for summary judgment of defendants TorPharm, [\*24] Inc., Apotex USA, Inc. and Apotex, Inc. [120-1] is granted in part and denied in part. Summary judgment is granted as to claim 2 of the '431 patent. Summary judgment is denied as to claim 1 of the '431 patent and as to Glaxo's declaratory judgment action.

(2) TorPharm is directed to file, within 10 days, a brief not to exceed 10 pages and supporting materials, if any, on the issue of whether a .5 amount of Form 2 RHCl in a mixture with Form 1 RHCl, would infringe claim 1 of the '431 patent. Glaxo may file a brief not to exceed 10 pages and supporting materials, if any, within 10 days thereafter. TorPharm may file a 5-page reply brief within 10 days thereafter.

(3) The stay entered in this case is vacated.

ENTER:

William T. Hart

UNITED STATES DISTRICT JUDGE

DATED: MAY 15, 1997

# **Exhibit D**

LEXSEE

**BENITEC AUSTRALIA LTD., Plaintiff, v. NUCLEONICS, INC., Defendant.**

**Civil Action No. 04-0174 JJF**

**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE**

**2005 U.S. Dist. LEXIS 22008**

**September 29, 2005, Decided**

**COUNSEL:** [\*1] John W. Shaw, Esquire, Glenn C. Mandalas, Esquire of YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware. Of Counsel: Marc R. Labgold, Esquire, Kevin M. Bell, Esquire, and Scott A. M. Changers, Esquire of PATTON BOGGS LLP, McLean, Virginia; Richard J. Oparil, Esquire of PATTON BOGGS LLP, Washington, District of Columbia, for Plaintiff.

Paul E. Crawford, Esquire of CONNOLLY, BOVE, LODGE & HUTZ, Wilmington, Delaware. Of Counsel: Dennis J. Mondolino, Esquire and Jason A. Lief, Esquire of MORGAN LEWIS & BOCKIUS LLP, New York, New York, for Defendant.

**JUDGES:** FARNAN, District Judge.

**OPINIONBY:** Joseph J Farnan Jr.

**OPINION:**

**MEMORANDUM OPINION**

September 29, 2005  
Wilmington, Delaware

Joseph J Farnan Jr.  
**FARNAN, District Judge**

Pending before the Court is the Motion For Voluntary Dismissal Without Prejudice (D.I. 108) filed by Plaintiff, Benitec Australia, Ltd. ("Benitec"). n1 For the reasons discussed, the Court will grant Benitec's motion.

n1 Defendant Nucleonics, Inc. filed an Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I. 117). The Court will grant the Motion, and the Surreply will be deemed filed.

[\*2]

**BACKGROUND**

The parties are engaged in conducting research and developing technologies to create therapeutics to treat disease using gene silencing technologies. On March 22, 2004, Benitec filed its Complaint (D.I. 1), alleging that Defendant, Nucleonics, Inc. ("Nucleonics"), infringes U.S. Patent No. 6,573,099 ("the '099 patent").

On February 16, 2005, Nucleonics files a Motion To Amend Its Answer to add seven declaratory judgment counterclaims of non-infringement, patent invalidity under 35 U.S.C. § 102, patent invalidity under 35 U.S.C. § 103, patent invalidity under 35 U.S.C. § 112(1), patent invalidity under 35 U.S.C. § 112(2), patent invalidity under 35 U.S.C. § 116, and patent unenforceability. (D.I. 91). On September 14, 2005, the Court issued an Order granting Nucleonics' Motion To Amend Its Answer (D.I. 119).

The parties have not yet completed discovery.

**PARTIES' CONTENTIONS**

By its motion, Benitec contends that this case should be dismissed without prejudice pursuant to Federal Rule of Civil Procedure 41(a) [\*3] because of a substantive change in the law with regard to the scope of the exemption set forth in 35 U.S.C. § 271(e)(1). Specifically, Benitec contends that the recent decision of the United States Supreme Court in Merck KGAA v. Integra Lifesciences I. Ltd., 162 L. Ed. 2d 160, 125 S. Ct. 2372 (2005), had the effect of negating the case or controversy before the Court with regard to infringement of Benitec's patents and, therefore, dismissal is warranted.

In response, Nucleonics contends that the Court retains jurisdiction to decide its counterclaims for invalidity, unenforceability, and non-infringement because Nucleonics has a reasonable apprehension of being sued by Benitec in the future. Nucleonics argues that, because

2005 U.S. Dist. LEXIS 22008, \*

Benitec filed a lawsuit for patent infringement against Nucleonics and Benitec has not provided Nucleonics with a covenant not to sue for past, present, and future acts, jurisdiction over the declaratory judgment counterclaims exists.

### LEGAL STANDARD

When a plaintiff moves for a dismissal without prejudice under Rule 41(a)(2), the decision to dismiss with prejudice or without is left to the discretion of the court. Buse v. Vanguard Group of Inv. Cos., 1994 U.S. Dist. LEXIS 3978, No. 91-3560, 1994 WL 111359, [\*4] at \*2 (E.D. Pa. Apr. 1 1994). Specifically, Rule 41(a)(2) provides: "An action shall not be dismissed at the plaintiff's instance save upon order of the court and upon such terms and conditions as the court deems proper. If a counterclaim has been pleaded by a defendant . . . the action shall not be dismissed against the defendant's objection unless the counterclaim can remain pending for independent adjudication by the court. Unless otherwise specified in the order, a dismissal under this paragraph is without prejudice." Fed. R. Civ. P. 41(a)(2) (2004). A Rule 41(a)(2) motion "will be determined after attempting to secure substantial justice to both parties." DuToit v. Strategic Minerals Corp., 136 F.R.D. 82 (D. Del. 1991) citing Lunn v. United Aircraft Corp., 26 F.R.D. 12, 14 (D. Del. 1960). Moreover, while considering the legitimate interests of both parties, the Court must bear in mind that a plaintiff's motion should be granted absent substantial prejudice to the defendant. Id. 1994 U.S. Dist. LEXIS 3978, [WL] at 10.

### DISCUSSION

The Court concludes that: dismissing Benitec's action would not cause substantial prejudice to Nucleonics [\*5] because no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonics' declaratory judgment claims against Benitec.

Nucleonics objects to dismissing Benitec's action without prejudice because Nucleonics contends that Benitec's action "brought a public cloud of uncertainty" over Nucleonics. (D.I. 110 at 2.) Thus, Nucleonics contends that Benitec should not now be allowed to leave the playing field, keeping its patent safe from scrutiny with regard to invalidity or unenforceability, while continuing to taint Nucleonics' current and future business and technology with the threat of another lawsuit. Nucleonics argues that the Declaratory Judgment Act, 28 U.S.C. § 2201, permits the Court to independently adjudicate Nucleonics' counterclaims.

The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." EMC Corp. v. Norand Corp., 89 F.3d 807,

810 (Fed. Cir. 1996). Nucleonics has the burden of establishing the existence of an actual case or controversy. See Cardinal Chemical Co. v. Morton Intern., Inc., 508 U.S. 83, 95, 124 L. Ed. 2d 1, 113 S. Ct. 1967 (1993). [\*6] When a party has actually been charged with infringement of a patent, there is, necessarily, a case or controversy adequate to support jurisdiction of a counterclaim pursuant to the Declaratory Judgment Act. Id. at 96. Furthermore, a counterclaim questioning the validity or enforceability of a patent raises issues beyond the initial claim for infringement. Id. The issue before the Court, then, is whether an actual controversy sufficient to support the Court's jurisdiction over Nucleonics' declaratory judgment counterclaims continues to exist if Benitec's patent infringement claim is dismissed.

Benitec contends that dismissing its infringement claim divests the Court of jurisdiction to hear the counterclaims. However, a number of courts have held that withdrawing a charge of infringement will not necessarily preclude the existence of an actual controversy, especially if, as here, the withdrawal occurs after the filing of the declaratory judgment action. See, e.g., C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 881 (Fed. Cir. 1983); Societe de Conditionnement v. Hunter Eng'g, 655 F.2d 938 (9th Cir. 1981). In turn, Nucleonics contends [\*7] that, because Benitec has refused to enter into a covenant not to sue for enforcement of the '099 patent against Nucleonics at a later time, an actual controversy necessarily exists. However, a patentee's refusal to promise not to enforce the patent, while "relevant to the [actual controversy] determination," is "not dispositive." BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 980 (Fed. Cir. 1993).

In the alternative, Nucleonics contends that it has a reasonable apprehension of suit because Benitec has already sued Nucleonics and others for patent infringement, Benitec has not promised not to assert the '099 patent against Nucleonics in the future, and Benitec has requested a voluntary dismissal of its action without prejudice. In reply, Benitec contends that Nucleonics has nothing to fear because Nucleonics' research activities are exempt from infringement liability pursuant to § 271(e)(1) and the Supreme Court's decision in Integra.

The test for determining whether an actual case or controversy exists in a declaratory judgment action involving patents is two-pronged. First, the defendant's conduct must have created on the part of the plaintiff a reasonable [\*8] apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the product or have prepared to produce that product. Indium Corp. v. Semi-Alloys, Inc., 781 F.2d 879 (Fed. Cir. 1985).

2005 U.S. Dist. LEXIS 22008, \*

With regard to the first prong, the Court concludes that Nucleonics has demonstrated a reasonable apprehension of suit. The factual background in this case is such that Nucleonics could be concerned that Benitec would, at some time, file a patent infringement suit against it. By suing Nucleonics and alleging that Nucleonics' technology is now covered by the Benitec's patent, Benitec has engaged in a course of conduct that shows a willingness to protect that technology. See, e.g., C.R. Bard v. Schwartz, 716 F.2d 874, 880-81 (Fed. Cir. 1983); Int'l Medical Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575, 229 U.S.P.Q. 278, 281 (Fed. Cir. 1986).

With regard to the second prong, production or preparation of a product. Nucleonics contends that its entire research effort is devoted to the RNAi area of technology and its [\*9] activities will ultimately leave the safe harbor created by Integra. Nucleonics further alleges that it anticipates beginning research on livestock diseases, which are unprotected by the safe harbor. In response, Benitec argues that future infringement is not ripe for adjudication because Benitec's product may never be approved by the FDA or may be approved in a form that does not implicate the claims of the '099 patent. (D.I. 115 at 18.)

The declaratory judgment plaintiff carries the burden of proving the existence of facts underlying its allegations of the existence of an actual controversy. Jervis B. Webb Co., 742 F.2d 1388, 1399 (Fed. Cir. 1984). On the record before it, the Court concludes that Nucleonics has not demonstrated that it has produced or has prepared to produce a product that would be the target of an infringement lawsuit by Benitec. At the time this lawsuit was filed, Nucleonics was several years away from obtaining FDA approval. Further, as argued by Benitec, there is no certainty that any product approved by the FDA would be the same product that was in clinical trials at the time this lawsuit was filed. And finally, Nucleonics has adduced [\*10] no evidence that it has under-

taken sales or marketing activity with regard to any product. For these reasons, the Court concludes that any threat of litigation that may have existed now lacks sufficient immediacy and reality to support declaratory judgment jurisdiction.

### CONCLUSION

In the circumstances presented here, the Court concludes that no actual controversy supports jurisdiction under the Declaratory Judgment Act for Nucleonics's declaratory judgment claims against Benitec with regard to the '099 patent. Accordingly, the Court will grant Benitec's Motion For Voluntary Dismissal Without Prejudice (D.I. 108).

An appropriate Order will be issued.

### ORDER

At Wilmington, this 29th day of September 2005, for the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. The Motion For Voluntary Dismissal Without Prejudice (D.I. 108) filed by Plaintiff, Benitec Australia, Ltd. is **GRANTED**.

2. Defendant Nucleonics, Inc.'s Unopposed Motion And Supporting Memorandum To File A Surreply in Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I. 117) is **GRANTED**.

3. The Surreply attached as Exhibit [\*11] 1 to the Unopposed Motion And Supporting Memorandum To File A Surreply In Opposition To Plaintiff's Motion For Voluntary Dismissal Without Prejudice (D.I. 117) is deemed filed.

Joseph J. Farnan Jr.

United STATES DISTRICT JUDGE